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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/734,196	12/12/2000	John D. Kalvelage	MULTI 9	4254

7590

03/26/2004

JOHN H. THOMAS, P.C.
1561 EAST MAIN STREET
RICHMOND, VA 23219

EXAMINER

FIDEI, DAVID

ART UNIT	PAPER NUMBER
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3728

DATE MAILED: 03/26/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/734,196

Applicant(s)

KALVELAGE ET AL.

Examiner

David T. Fidei

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 February 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-17 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

On Remand to the Examiner

ITEM 1. The Administrative Patent Judges find nothing in the record setting forth what the terminology “impermeable seal” added to the amendment filed April 25, 2002 is intended to mean. Accordingly, the following is applied.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 1-17 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The specification fails provide support for an “impermeable seal”. At the very least some permeability is permitted in the package disclosed, hence there is no enabling description of such subject matter.

As to claims 11 and 12, it is not clear how the sealed blister is constructed to meet the requirements of a U.S.P. Class A or Class B container. No relative sizes of the blister components are taught, it is not clear what tolerances are required of the seal or how close the components should fit together to achieve the requirements of a U.S.P. Class A or Class B container. Without undue experimentation, the specification fails to provide an enabling disclosure of claims 11 and 12.

3. Claims 1-17 rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The specification fails to provide support for an “impermeable seal” as at the very least some

permeability is permitted. This would indicate applicant, at the time the application was filed, did not have possession of the invention as claimed.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1, 3, 9-14, 16 and 17 are rejected under 35 U.S.C. 102(b) as being anticipated by Allers et al (Patent no. 5,860,549). A sealed blister assembly is disclosed comprising a plastic sheet formed with a recess 25 having an undercut 44. An equivalent lid 12 is attached to cover the opening of the recess. The lid includes a raised ridge 28 adapted to engage the undercut of the plastic sheet.

With respect to claim 3 the ridge 28, i.e., as shown in figure 2a, has walls on both sides leading to the top of arc that flare outwardly. Similarly, the undercut also has "sidewalls" on either side leading to the arc in the bottom of recess 44 to the extent recited in claim 4, see e.g., figure 2B.

With respect to claim 10 the undercut sidewalls are shorter than the ridge wall because the ridge walls fit within the undercut and extends beyond and out of the undercut, note figure 4.

In as much as claims 11 and 12 recite the blister assembly meet or exceed the requirements of a Class A or Class B container, it is not seen what is defined within this language that distinguishes the present subject matter based upon the recited comparison. Otherwise stated, in the form drafted, it would appear subject matter meeting claim 1 would also meet claims 11 and 12 since the examiner knows of no measurable parameter serving to provide a distinction based upon this language.

As to claim 13 a planar shoulder 42 is formed along the peripheral portion of the sheet used to form the recess 25. A perimeter is also formed around the recess. Also, since the recess of Allers et al is fully capable of receiving medication, this is merely a matter of intended use. A reference that contains all the structure defined in a claim, but not the recited use anticipates the claim because a new use does not make an old product patentable, *In re Schreiber*, 128 F.3d 1473, 44 U.S.P.Q.2d 1429 (Fed. Cir. 1997).

As to claims 16 and 17 the length and width dimensions of the ridge 28 of Allers et al is considered larger than the corresponding dimensions of the undercut to the same extent as that shown in figure 2 of the present invention. Particularly in light of the undercut outside wall taper resulting in a lesser dimension than the outermost dimension of the ridge.

ITEM 2. Clarification and explanation is required of the examiner for the proposition that a “mere matter of intended use” does not explain how the specific combination of claim 13 is anticipated by Allers and Edwards. The examiner points out claim 13 attempts to distinguish over these prior art references (Allers and Edwards) by reciting “*a pharmaceutical medication positioned in said recess of said plastic sheet*”.

This language sets forth no specific structural details of the container.¹ In fact, such a distinction is a mere matter of intended use as one can place any number of objects within the container, none of which that would serve to provide any structural distinction based on a particular use. Furthermore, it is believed the reference to *In re Schreiber*, 128 F.3d 1473, 44 U.S.P.Q.2d 1429 (Fed. Cir. 1997) is particularly relevant.

In *Schreiber* a dispensing top for passing only several kernels of popped corn was held *anticipated* by a spout dispensing oil from an oil can. Despite *Schreiber* claiming an open ended container filled with popped corn and submitting evidence that the oil can spout was incapable of jamming up the popped corn permitting only a few kernels at a shake of a package. In dissenting

¹ .a thing consisting of a number of elements joined together in a certain way. Wordsmyth Dictionary-Thesaurus.

from the majority opinion Judge Newman points out "the Board held that it is irrelevant that the Schreiber claims are to a *container filled with popped corn* (emphasis mine)", In re Schreiber, 44 U.S.P.Q.2d at 1434 (Fed. Cir. 1997). Hence, the fact scenario is clearly relevant to the claims at bar.

While the medication recited in claim 13 is positioned in the recess, claims for a package assembly which contains *all* the structural limitations recited in the application is anticipated by the containers of Allers and Edwards used to dispense food, even though they do not address the use of their (Allers and Edwards) containers to dispense medication. Since, Schreiber stands for the contention that a structure used to dispense a different product does not have patentable weight if the structure is already known, In re Schreiber, 44 U.S.P.Q.2d at 1431.

In light of the forgoing clarification, it is believed the original holding of the examiner is now made more clear.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 13, 14 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Allers et al (Patent no. 5,860,549). A sealed blister assembly is disclosed comprising a plastic sheet formed with a recess 25 having an undercut 44. An equivalent lid 12 is attached to cover the opening of the recess. The lid includes a raised ridge 28 adapted to engage the undercut of the plastic sheet. As to claim 13 a planar shoulder 42 is formed along the peripheral portion of the sheet used to form the recess 25. A perimeter is also formed around the recess. The difference between Allers et al and claimed subject matter of resides in a pharmaceutical medication positioned in the recess of the plastic sheet.

It would have been obvious to one of ordinary skill in the art to modify the blister of Allers et al by placing any item desired, including pharmaceutical medication, within the blister as a matter of routine skill and intended use.

As to claim 17 the length and width dimensions of the ridge 28 of Allers et al is considered larger than the corresponding dimensions of the undercut to the same extent as that shown in figure 2 of the present invention. Particularly in light of the undercut outside wall taper resulting in a lesser dimension than the outermost dimension of the ridge.

8. Claims 4 and 5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Allers et al as applied to claims 1 and 3 above, and further in view of Edwards et al (Patent no. 5,339,973). The difference between Allers et al and the subject matter of these claims resides in the undercut having sidewalls that are in frictional engagement with the outside edge of the ridge wall. Edwards is cited for the motivational teaching of figures 6-8 and column 3, lines 5-11.

To the extent that Allers et al fails to teach an undercut having sidewalls that are in frictional engagement with the outside edge of the ridge wall, the prior art fairly teaches such a modification in order to provide a tight seal between the tray and lid. Accordingly, modifying Allers et al by constructing sidewalls in frictional engagement with the outside edge of the ridge walls would not have involved an inventive step.

ITEM 3. Since there is an abundance of prior art references showing polyethylene to be a well known plastic material to those skilled in the container art, the rejection over Allers et al has been modified in the manner suggested by the Board, i.e., 35 U.S.C. 103 not 35 U.S.C. 102(b).

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9. Claims 6-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Allers et al (Patent no. 5,860,549) as applied to claims 1 and 3 above, and further in view of Cox (Patent no. 5,803,248). The difference between the claimed subject matter and Allers resides in the sealed blister comprised of polyethylene.

Cox Patent no. 5,803,248 column 3, line 28 discloses the use P.E.T. (polyethylene terephthalate) in blister packs. It would have been obvious to one of ordinary skill in the art to use a plastic sheet comprised of polyethylene as suggested by Cox, for the reason of moisture and air impermeability imparted by the material.

ITEM 4. On remand the examiner is required to provide an explanation of exactly what these limitations (U.S.P. Class A or Class B container requirements) mean in the context of claims 11 and 12 on appeal as disclosed by appellant, or direct applicant to do so. Since it would appear inappropriate for the examiner to define exactly what applicant's intentions are, the requirement is deferred to applicant.

However, the examiner does consider that *all* of the limitations in the claims have been treated in an appropriate rejection. It's not that these limitations have read out of the claims, rather the subject matter adds no patentable moment. Again, a package recited as used for packaging a medication and the sealed blister meets or exceeds the requirements to be a U.S.P. Class A , or Class B individual unit-dose container, does nothing to distinguish such subject matter over subject matter meeting all of the structural limitation.

Claim Rejections - 35 USC § 112

10. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

11. Claims 11 and 12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is unclear what exactly are the requirements of a U.S.P. Class A or Class B individual unit-dose container, see item 4 of Remand. Whether a certain permeability rate is required, if the permeability is a result of using a certain material having a required thickness, a result of a seal of specified tightness or the result of a combination of all these factors.

ITEM 5. The reference to Allers in establishing the rejection 35 U.S.C. 102(b) as being anticipated by Edwards et al is regretted. Upon remand appropriate portions of the Edwards is used throughout the rejection.

12. Claims 1, 3-10, 13, 14, 16 and 17 are rejected under 35 U.S.C. 102(b) as being anticipated by Edwards et al (Patent no. 5,339,973). Edwards discloses a sealed blister comprising a plastic sheet formed with a recess having an undercut 40. An equivalent lid 12 is attached to cover the opening of the recess. The lid includes a raised ridge 38 adapted to engage the undercut of the plastic sheet. Figures 8 and 9 show other embodiments having similar constructions.

As to claim 13 a planar shoulder 42 is formed along the peripheral portion of the sheet used to form the recess 25. A perimeter is also formed around the recess. Also, since the recess of Edwards et al is fully capable of receiving medication, this is merely a matter of intended use. A reference that contains all the structure defined in a claim, but not the recited use anticipates the claim because a new use does not make an old product patentable, *In re Schreiber*, 128 F.3d 1473, 44 U.S.P.Q.2d 1429 (Fed. Cir. 1997).

As to claims 16 and 17 the length and width dimensions of the ridge 38 is considered larger than the corresponding dimensions of the undercut to the same extent as that

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shown in figure 2 of the present invention. Particularly in light of the undercut outside wall taper resulting in a lesser dimension than the outermost dimension of the ridge.

13. Claims 13, 14 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Edwards et al (Patent no. 5,339,973). Edwards discloses a sealed blister comprising a plastic sheet formed with a recess having an undercut 40. An equivalent lid 12 is attached to cover the opening of the recess. The lid includes a raised ridge 38 adapted to engage the undercut of the plastic sheet. Figures 8 and 9 show other embodiments having similar constructions. As to claim 13 a planar shoulder 42 is formed along the peripheral portion of the sheet used to form the recess 25. A perimeter is also formed around the recess.

It would have been obvious to one of ordinary skill in the art to modify the blister of Edwards et al by placing any item desired, including pharmaceutical medication, within the blister as a matter of routine skill and intended use.

As to claim 17 the length and width dimensions of the ridge 38 is considered larger than the corresponding dimensions of the undercut to the same extent as that shown in figure 2 of the present invention. Particularly in light of the undercut outside wall taper resulting in a lesser dimension than the outermost dimension of the ridge.

14. Claims 2 and 15 rejected under 35 U.S.C. 103(a) as being unpatentable over Zimmerman et al (Patent no. 6,039,495) in view of Allers et al (Patent no. 5,860,549). Zimmerman discloses a sheet having a plurality of recesses with individual lids sealing the same. The difference between the claimed combination resides in the undercut formed in the perimeter all around the recess. Allers discloses such sealing arrangement in figures 2A. It would have been obvious to one of ordinary skill in the art to modify the sealing arrangement of Zimmerman by constructing an undercut engaging a raised ridge as taught by Allers et al, in order to form a seal in the opening that provides a tighter engagement around the entire periphery.

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15. Claims 2 and 15 rejected under 35 U.S.C. 103(a) as being unpatentable over Zimmerman et al (Patent no. 6,039,495) in view of Edwards et al (Patent no. 5,339,973). Zimmerman discloses a sheet having a plurality of recesses with individual lids sealing the same. The difference between the claimed combination resides in the undercut formed in the perimeter all around the recess. Edwards discloses such sealing arrangement in figures 6-9. It would have been obvious to one of ordinary skill in the art to modify the sealing arrangement of Zimmerman by constructing an undercut engaging a raised ridge as taught by Edwards, in order to form a seal in the opening that provides a tighter engagement around the entire periphery.

REPLY BY APPLICANT OR PATENT OWNER TO THIS OFFICE ACTION

14. "In order to be entitled to reconsideration or further examination, the applicant or patent owner must reply to every ground of objection and rejection in this Office action. The reply must present arguments pointing out the specific distinctions believed to render the claims, including any newly presented claims, patentable over any applied references. The applicant's or patent owner's reply must appear throughout to be a bona fide attempt to advance the application or the reexamination proceeding to final action. A general allegation that the claims define a patentable invention without specifically pointing out how the language of the claims patentably distinguishes them from the references does not comply with the requirements of this section. The reply must be reduced to writing (emphasis added)", see 37 CFR 1.111 (b) & (c), M.P.E.P. 714.02.

Pointing out specific distinctions means clearly indicating in the written response what features/elements or distinctions have been added to the claim/claims, where support is found in the specification for such recitations and how these features are not shown, taught, obvious or inherent in the prior art.

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If no amendments are made to claims as applicant or patent owner believes the claims are patentable without further modification, the reply must distinctly and specifically point out the supposed errors in the examiner's action and must respond to every ground of objection and rejection in the prior Office Action in the same vain as given above, 37 CFR 1.111 (b) & (c), M.P.E.P. 714.02.

The examiner also points out, due to the change in practice as affecting final rejections, older decisions on questions of prematurity of final rejection or admission of subsequent amendments do not necessarily reflect present practice. "Under present practice, second or any subsequent actions on the merits shall be final, except where the examiner introduces a new

ground of rejection that is neither necessitated by applicant's amendment of the claims nor based on information submitted in an information disclosure statement filed during the period set forth in 37 CFR 1.97(c)" (emphasis mine), see MPEP 706.07(a).

Conclusion

15. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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If in receiving this Office Action it is apparent to applicant that certain documents are missing, e.g., copies of references cited, form PTO-1449, form PTO-892, etc., requests for copies of such papers or other general questions should be directed to Tech Center 3700 Customer Service at (703) 306-5648, email CustomerService3700@uspto.gov.

Any inquiry concerning the MERITS of this examination from the examiner should be directed to David T. Fidei whose telephone number is (703) 308-1220. The examiner can normally be reached on Monday, Thursday and Friday 8:30 am - 6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mickey Yu can be reached at (703) 308-2672.

Effective Monday morning, August 4, 2003, all official faxes for the TCs will be received in one central location in the Office. In cooperation with the Customer Service Goal Team, a new central official fax number (703-872-9306) has been established for use by the TCs. An OG notice will be issued and the Website updated to alert PTO customers of the new fax number. Official standalone (non-RightFax) fax machines will be removed from the TC fax centers, their phone numbers auto-forwarded to a single RightFax account, and faxes printed in the centralized fax center.

Other helpful telephone numbers are listed for applicant's benefit.

Allowed Files & Publication	(703) 305-8497
Assignment Branch	(703) 308-9723
Certificates of Correction	(703) 305-8309
Drawing Corrections/Draftsman	(703) 305-8404/8335
Fee Increase Questions	(703) 305-5125
Intellectual Property Questions	(703) 305-8217
Petitions/Special Programs	(703) 305-9282
Terminal Disclaimers	(703) 305-8408

If the information desired is not provided above, or has been changed, please do not call the examiner (this is the latest information provided to him) but the general information help line below.

Information Help line	1-800-786-9199
Internet PTO-Home Page	http://www.uspto.gov/

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David T. Fidei
Primary Examiner
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March 23, 2004